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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/683,658

10/09/2003

Eugene de Juan JR.

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07/29/2008

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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

07/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/683,658	Applicant(s) JUAN ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,31-37 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,31-37 and 42-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/29/2008</u> | 6) ☐ Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 04/09/2008. These drawings are accepted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 29, 31, 32, 35-37, 42, 44-46, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banko (US 3,659,607) in view of Peyman (US 5,487,725).

Regarding claims 29 and 31, Banko discloses an entry alignment device (Fig. 2, element 50) configured for insertion into an eye so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure (Column 2, lines 45-47 and 54-56). Banko fails to disclose the alignment device is sized such that when the entry alignment device is removed from the eye, the entry aperture formed in the sclera is sealed without the use of sutures. Peyman discloses that small instrument size (25 gauge; Column 10, lines 2-5) allows the surgical wound in they eye wall to be self-sealing (Column 5, line 15) and reduces the recovery period following surgery (Column 4, lines 53-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to reduce the size of the device of Banko as taught by Peyman so that the aperture formed is small enough to be self-sealing in order to reduce recovery time.

Regarding claim 32, Banko does disclose a surgical instrument having an operable end with the cross-sectional diameter not greater than 25 gauge. Peyman teaches a vitreous cutter (202) having an operable end with a cross-sectional diameter of a 25-gauge needle (Column 10, lines 2-5). Peyman discloses that smaller instruments are desirable because they cause less damage to the eye and no sutures are needed to seal the entry aperture (Column 4, lines 53-55). Therefore, it would have been obvious to one of ordinary skill in the art to have included an instrument with a maximum cross-sectional diameter of a 25 gauge needle for disposal in the entry alignment device of Banko to be used during vitreoretinal procedures because it would minimize the damage to the eye and the patient's recovery time.

Regarding claim 35, Banko does not teach an infusion cannula. However, Peyman discloses an infusion cannula, having the diameter of a 20 to 30-gauge needle, to maintain intraocular pressure during vitrectomy procedures (Column 5 lines 30-35, Column 10, lines 35-40). It would have been obvious to one of ordinary skill in the art to include a 25-gauge infusion cannula in order to maintain pressure while causing as little trauma to the eye as possible.

Regarding claim 36, an entry alignment device (50) configured to be in the form of a metal cannula (Fig. 2; Column 5, line 11).

Regarding claim 37, Banko does not disclose a surgical instrument selected from a group of a forceps, scissors, pick, light source, laser, fragmentation device, diathermy device, and aspirator. Peyman discloses a 25 gauge vitreous cutter (202), taken to be a fragmentation device/aspirator, for repairing a detached retina. It would have been obvious to one of ordinary skill in the art to supply a fragmentation device or aspirator to

be disposed with the aperture created by the entry alignment device of Banko in order to repair a detached retina while minimizing damage to the eye wall.

Regarding claim 42, Banko discloses an insertion tool (70) including a penetrating member (76) and at least one entry alignment device (50) configured for insertion into an eye so as to be removably mounted (Column 5, lines 57-61) to the insertion tool penetrating member and so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure (Column 2, lines 45-47 and 54-56). Banko fails to disclose the alignment device is sized such that when the entry alignment device is removed from the eye, the entry aperture formed in the sclera is one of self-sealing or sealed without the use of sutures. Peyman discloses that small instrument size (25 gauge; Column 10, lines 2-5) allows the surgical wound in they eye wall to be self-sealing (Column 5, line 15) and reduces the recovery period following surgery (Column 4, lines 53-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to reduce the size of the device of Banko to a cross-sectional diameter of 25 gauge of Banko as taught by Peyman so that the aperture formed is small enough to be self-sealing in order to reduce recovery time.

Regarding claim 44, Banko in view of Peyman discloses an the entry alignment device configured so as to include an aperture that is sized to receive therein surgical instruments having a cross-sectional diameter not more than 25 gauge.

Regarding claim 45, an insertion tool being provided with a handle member (72), where the penetrating member extends from an end of the handle member.

Regarding claim 46, an insertion tool further including a mechanism (78) for removably securing the entry alignment device to the insertion tool (Column 5, lines 57-61).

Regarding claim 51, Banko discloses an insertion tool (70) including a penetrating member (76) and at least one entry alignment device (50) configured for insertion into an eye so as to be removably mounted (Column 5, lines 57-61) to the insertion tool penetrating member and so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure (Column 2, lines 45-47 and 54-56); wherein the penetrating member is configured and arranged so as to be inserted through each of the conjunctiva and the sclera. Banko fails to disclose the penetrating member configured so as to form an opening in the sclera of a size such that the sutures are not needed to prevent fluid escaping from within the eye while the entry alignment device is disposed in the opening in the conjunctiva and the sclera during the procedure. Peyman discloses that small instrument size (25 gauge; Column 10, lines 2-5) allows the surgical wound in the eye wall to be self-sealing (Column 5, line 15) and reduces the recovery period following surgery (Column 4, lines 53-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to reduce the size of the device of Banko to a cross-sectional diameter of 25 gauge of Banko as taught by Peyman so that the aperture formed is small enough to be self-sealing in order to reduce recovery time. Banko in view of Peyman discloses the penetrated member sized such that sutures are not needed to prevent fluid escaping from within the eye while the entry alignment device is disposed in the opening in the conjunctiva and the sclera during the surgical procedure.

Regarding claim 52, Banko discloses an entry alignment device (Fig. 2, element 50) configured for insertion into an eye so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure (Column 2, lines 45-47 and 54-56). Banko fails to disclose the alignment device is configured and arranged such that the entry aperture formed in each of the conjunctiva and the sclera when the entry alignment device is inserted therein is of a size such that the sutures are not needed to prevent fluid escaping from within the eye while the entry alignment device is disposed in the opening in the conjunctiva and the sclera during the surgical procedure. Peyman discloses that small instrument size (25 gauge; Column 10, lines 2-5) allows the surgical wound in the eye wall to be self-sealing (Column 5, line 15) and reduces the recovery period following surgery (Column 4, lines 53-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to reduce the size of the device of Banko to a cross-sectional diameter of 25 gauge of Banko as taught by Peyman so that the aperture formed is small enough to be self-sealing in order to reduce recovery time. Banko in view of Peyman disclose the entry aperture is of a size such that sutures are not needed to prevent fluid escaping from within the eye when the entry alignment device is disposed in the opening in the conjunctiva and the sclera.

4. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banko (US 3,659,607) and Peyman (US 5,487,725) as applied to claim 32 above, and further in view of Oberkamp (US 6,485,499).

Regarding claims 33 and 34, Banko does not teach a high-speed vitreous cutter. However, Peyman discloses a 25 gauge vitreous cutter (Fig. 10, element 202) capable of cutting and aspirating material through the operable end portion (Column 4, line 40-

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44). Peyman teaches a vitreous cutter including an insertion member (Fig. 8, element 204) having a lumen (222) therein and an aperture (Fig. 2, element 224) at the proximal end thereof; a cutting member (232) disposed in the lumen; and a cutting member driving mechanism being mechanically interconnected to the cutting member that causes the cutting member to move cyclically in an axial direction within the lumen (Column 9, line 52 – Column 10, line 6). Peyman also discloses that smaller instruments are more desirable because they decrease recovery time (Column 4, lines 53-55). It would have been obvious to one of ordinary skill in the art to include a vitreous cutter as disclosed by Peyman to be used within the self-sealing aperture created with the entry alignment device taught by Banko to remove break-up and remove vitreous material from the eye during surgery to repair a detached retina. Peyman fails to disclose a cutting member driving mechanism capable of driving the cutting member 1000 cuts per minute past the insertion member (Column 3, lines 20-27). However, Oberkamp teaches a driving mechanism capable of driving the cutter 1000 cuts per minute (Column 3, lines 24-27). Oberkamp discloses that stroke rate should depend on the particular surgical application and a high stroke rate is preferable for when all or some of the vitreous is to be removed (Column 3, lines 31-35). Therefore, it would have been obvious to provide a vitreous cutter capable of cutting 1000 cuts per minute to be used within the aperture created by the device of Banko in order to provide a more desirable cutting rate for the removal of vitreous material.

5. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banko (US 3,659,607) and Peyman (US 5,487,725) as applied to claim 42 above, and further in view of Saperstein et al. (US 5,919,158).

Regarding claims 47 and 48, Banko discloses an insertion tool having one penetrating member for a single entry alignment device. However, Banko does not teach a plurality of entry alignment devices and a plurality of penetrating members. Saperstein discloses a need to use instruments simultaneously within the eye (Column 1, lines 17-21). Specifically, Saperstein teaches a light probe (32) within the eye to allow the surgeon to view where he or she is working with another instrument during vitreoretinal procedures (Column 5, lines 13-15). Therefore, multiple entry alignment devices would be desirable to create and maintain multiple apertures simultaneously. It would have been obvious to one of ordinary skill in the art to include multiple entry alignment devices, each mounted on one of the multiple penetrating members, for creating multiple apertures in order to dispose within the eye both a light probe and any other appropriate surgical tool such as a vitreous cutter or forceps so the surgeon would be able to see the site where the other instrument(s) are being used.

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banko (US 3,659,607) and Peyman (US 5,487,725) as applied to claim 42 above, and further in view of Sutherland (US 4,258,716).

Regarding claim 49, Banko does not disclose a forceps. However, Sutherland teaches microsurgical forceps including: a first member (Figure 11, element 55) having a lumen and a fixed sloping end (56) proximal an end of open lumen, a second member (57) being disposed in the lumen and being axially movable therein, the second member having a sloped end (58), and wherein the first and second member are arranged so that the fixed sloping end opposes the second member sloping end (Figure 11; Column 5, lines 29-43). Sutherland discloses that the forceps are small enough to enter an aperture in the eye and capable of being manipulated at different angles relative to the aperture

(Column 3, lines 3-5, 10-12). Therefore, it would have been obvious to one of ordinary skill in the art to include the forceps as described by Sutherland to be used within aperture created by the device of Banko in order to manipulate tissue within the eye.

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banko (US 3,659,607) and Peyman (US 5,487,725) as applied to claim 42 above, and further in view of Oberkamp (US 6,485,499).

Regarding claim 50, Banko modified by Peyman discloses the invention as stated above. Peyman further teaches a 25 gauge vitreous cutter (Fig. 10, element 202) including an insertion member (Fig. 8, element 204) having a lumen (222) therein and an aperture (Fig. 2, element 224) at the proximal end thereof; a cutting member (232) disposed in the lumen; and a cutting member driving mechanism being mechanically interconnected to the cutting member that causes the cutting member to move cyclically in an axial direction within the lumen (Column 9, line 52 – Column 10, line 6). Peyman also discloses that smaller devices are more desirable because they decrease recovery time (Column 4, lines 53-55). It would have been obvious to one of ordinary skill in the art to include a vitreous cutter as disclosed by Peyman to be used within the aperture created with the entry alignment device taught by Banko to remove break-up and remove vitreous material from the eye. Banko modified by Peyman does not disclose a cutting member driving mechanism capable of driving the cutting member 1000 cuts per minute past the insertion member (Column 3, lines 20-27). However, Oberkamp teaches a driving mechanism capable of driving the cutter 1000 cuts per minute (Column 3, lines 24-27). Oberkamp discloses that stroke rate should depend on the particular surgical application and a high stroke rate is preferable when all or some of the vitreous is to be removed (Column 3, lines 31-35). Therefore, it would have been obvious to

provide a vitreous cutter capable of cutting 1000 cuts per minute to be used within the aperture created by the device of Banko in order to provide a more desirable cutting rate for the removal of vitreous material.

Response to Arguments

8. Applicant's arguments filed 4/9/08 have been fully considered but they are not persuasive. In response to applicant's argument that the device of Banko is not an entry alignment device configured to provide an entry aperture in each of the conjunctiva and the sclera and so as to maintain such apertures aligned during a surgical procedure, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to applicant's argument that the device of Banko would not create an aperture which is self-sealing. The examiner agrees that the device of Banko alone would not create an aperture which is self-sealing. However, in view of Peyman's teaching that small instrument size (25 gauge; Column 10, lines 2-5) allows the surgical wound in they eye wall to be self-sealing (Column 5, line 15) and reduces the recovery period following surgery (Column 4, lines 53-55), it would have been obvious to make the device of Banko smaller (25 gauge) to create a self-sealing aperture and reduce the recovery period. In view of applicant's disclosure, a penetrating member, having a cross-sectional diameter of 25 gauge, is sized to be self-sealing. Therefore, the device of Banko modified by Peyman is capable of creating a self-sealing aperture. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to applicant's argument that Peyman fails to teach an incision which is self-sealing, Peyman discloses the incision is capable of self-sealing (col. 5, ln. 15). In any event, Peyman discloses instruments having cross-sectional diameters of 23-25 gauge, which meets the structure which applicant discloses as being small enough for an incision to be self-sealing (page 15, ln. 8-12, page 18, ln. 12). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to applicant's argument that there is no suggestion to combine the references of Banko, Oberkamp, Sutherland, and Saperstein, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the instruments of Oberkamp, Sutherland, and Saperstein may be used together in the same surgical procedure with the entry alignment device of Banko providing access of the instruments to the surgical site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
7/09/08

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731